Deciding on Optimal Approach for Ventral Hernia Repair: Laparoscopic or Open

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BACKGROUND: The decision to perform laparoscopic or open ventral hernia repair (VHR) is multifactorial. This study evaluates the impact of operative approach, BMI, and hernia size on outcomes after VHR.

STUDY DESIGN: The International Hernia Mesh Registry was queried for VHR (2007-2017). A predictive algorithm was constructed, factoring the impact of BMI, hernia size, age, sex, diabetes, and operative approach on outcomes.

RESULTS: Of the 1,906 VHRs, 58.8% were performed open, patient mean age was 54.9 ± 13.5 years, BMI was 31.2 ± 6.8 kg/m^2, and defect area was 44.8 ± 88.1 cm^2. Patients undergoing open VHRs were more likely to have an infection develop (3.1% vs 0.3%; $p < 0.0001$), but less likely to have a seroma develop (6.8% vs 15.3%; $p < 0.0001$) at mean follow-up 23.2 ± 12.0 months. With multivariate regression controlling for confounding variables, patients undergoing laparoscopic VHR had increased risk of seroma (odds ratio [OR] 1.78; 95% CI 1.05 to 3.03), a decreased risk of infection (OR 0.05; 95% CI 0.01 to 0.42), and had worse quality of life at 1, 6, 12, and 24 months postoperatively compared with patients undergoing open repair. Recurrent hernias were associated with subsequent recurrence (OR 2.69; 95% CI 1.24 to 5.81) and need for reoperation (OR 4.93; 95% CI 2.24 to 10.87). Multivariate predictive models demonstrated independent predictors of infection, including open approach, recurrent hernias, and low ratio of BMI to defect size.

CONCLUSIONS: Ideal outcomes are dependent on both patient and operative factors. Open repair in thin patients with large defects should be considered due to reduced complications and improved quality of life. Laparoscopic repair in obese patients and recurrent hernias can decrease the associated risk of infection. (J Am Coll Surg 2019;228:54–65. © 2018 by the American College of Surgeons. Published by Elsevier Inc. All rights reserved.)

Since first described in the 1990s, laparoscopic ventral hernia repair (LVHR) has been established to be a safe and effective approach to VHR. As of 2013, LVHR accounted for only 26.6% of VHRs performed in the US, and was shown to be associated with decreased length of stay and hospital charges.[1] Although multiple studies have compared the outcomes of both LVHR and open ventral hernia repair (OVHR), the optimal operative approach, as determined by short and long-term outcomes, continues to be controversial.[2-6]

The laparoscopic approach most dramatically benefits patients with relatively small defects (<5 cm), who have shorter length of stay and lower rates of surgical site infections compared with OVHR.[3,6-13] The decreased rate of surgical site infections is more pronounced when LVHR is performed in obese patients.[4,14-16] The downsides of

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Abbreviations and Acronyms

AUC = area under receiver operating characteristic curve
CCS = Carolinas Comfort Scale
IHMR = International Hernia Mesh Registry
IQR = interquartile range
LVHR = laparoscopic ventral hernia repair
OR = odds ratio
OVHR = open ventral hernia repair
QOL = quality of life
VIF = variance inflation factor

laparoscopic repair include a higher incidence of seromas and worse short-term quality of life (QOL) compared with OVHR, with long-term postoperative QOL similar between LVHR and OVHR.[6,8,17-21] Studies have shown higher, lower, or no significant difference in recurrence rates between laparoscopic and open approaches.[6,13,22-27] Although closure of midline fascia during LVHR with mesh has lower recurrence rates compared with bridging abdominal wall defects, there are no studies to date investigating postoperative QOL with closure of the midline fascia. These variable operative techniques can further compound comparison of outcomes, with factors such as primary fascial closure, location of mesh placement, and method of mesh fixation often not reported or controlled for.

Operative approach is a complex decision influenced by defect size, previous operations, patient comorbidities, and surgeon training and preference. The aim of this study was to determine the optimal operative approach when considering a patient's hernia defect size, BMI, history of recurrence, diabetes, and other operative risk factors. Using a prospective, international hernia registry, including a hernia-specific QOL assessment tool, a predictive algorithm for operative outcomes was constructed to assist in determining the optimal approach. The ideal surgical approach will optimize postoperative QOL and minimize postoperative complications and hernia recurrence.

METHODS

International Hernia Mesh Registry

Data were retrieved and analyzed from the International Hernia Mesh Registry (IHMR). This is a multinational, observational, prospective database of hernia repairs performed with mesh in more than 30 centers across North America, South Africa, Europe, and Australia. The IHMR is a registered clinical trial with ClinicalTrials.gov, ID NCT00622583 (http://www.clinicaltrials.gov/ct2/show/study/NCT00622583).[19,28] Inclusion and exclusion criteria have been described previously and are included in Table 1.[19,28] Trained abstractors at each participating facility collect and enter consecutive patient data, and the information is held and evaluated by an independent, third-party data management company (Outcome Sciences, Inc). Data collected include patient demographics, comorbidities, hernia details (recurrence, location, and defect size), operative details (laparoscopic or open approach, mesh type and placement, fixation technique, and operative time), and postoperative outcomes, including length of stay, complications, recurrence, and QOL. Pre- and postoperative QOL surveys are completed at home or in the office without the presence of healthcare personnel to guarantee anonymity and minimize observer and collection bias. Patients are provided with a $10 voucher to encourage participation in postoperative follow-up.

Table 1. Inclusion and Exclusion Criteria for Participation in International Hernia Mesh Registry

Inclusion criteria
Male or female patients that are 18 years of age or older, and will provide written informed consent
Be literate and able to understand a language available in the registry patient questionnaires
Be scheduled to receive a surgically implanted mesh product (synthetic or biologic)
Agree to provide long-term outcomes data to Outcome Sciences, Inc
Agree to provide contact information
Exclusion criteria
Younger than 18 y of age
Have been entered into the registry previously
Employees of the investigator or registry center with direct involvement in the proposed registry or other studies under the direction of that investigator or registry center and employees of Ethicon, Inc
Suffering from and currently receiving medication for chronic pain
Known to be suffering from pre-existing chronic depression
Currently known or suspected to abuse drugs or alcohol
Suffering from a terminal illness
Requiring multiple hernia repairs using more than one mesh or device, except bilateral inguinal or femoral, if operated on the same day. Two or more pieces of the same mesh product sewn together will be considered as one mesh and is therefore allowed
Scheduled to receive both a synthetic and biologic mesh during the same procedure
Requiring any other (concomitant) surgical procedure
Suffering from an ongoing infection

Table 2. Demographic Characteristics of Patients Undergoing Ventral Hernia Repair with Mesh

Characteristic	All	Open VHR (n = 1,120 [58.8%])	Laparoscopic VHR (n = 786 [41.2%])	p Value*
Comorbidities				
BMI, kg/m^2, median (IQR)	30.1 (26.5–35.1)	29.4 (26.0–33.9)	31.6 (27.6–36.5)	<0.0001†
Age, y, median (IQR)	56 (46–65)	56 (45.5–65)	55 (46–65)	0.80
Female, %	44.1	38.4	52.2	<0.0001†
White, %	88.3	93.6	80.6	<0.0001†
Diabetes, %	13.5	13.3	13.8	0.92
Steroid, %	2.48	2.60	2.30	0.77
Current smoker, %	18.1	19.9	16.8	0.0003†
Hernia characteristic				
Ventral, %	58.9	54.1	65.8	<0.0001†
Epigastric, %	6.1	6.7	5.2	<0.0001†
Umbilical, %	29.8	36.1	20.7	<0.0001†
Other, %	5.2	3.1	8.3	
Width, cm, mean ± SD	5.3 ± 4.9	5.1 ± 5.3	5.5 ± 4.3	<0.001†
Length, cm, mean ± SD	6.4 ± 6.3	6.0 ± 6.6	6.9 ± 5.9	<0.001†
Area, cm^2, mean ± SD	44.8 ± 88.1	46.6 ± 104.5	42.6 ± 61.9	<0.0001†
Recurrent hernia, %	17.1	16.3	18.1	0.32
1 previous repair	63	61	65.7	<0.001†
2 previous repairs	24.2	28	19.3	<0.001†
Fascial defect closure, %	52.1	72.2	30.0	<0.0001†

*Univariate analysis by operative approach.
†Significant.
IQR, interquartile range; VHR, ventral hernia repair.

Outcomes assessment

The IHMR was queried for patients undergoing LVHR and OVHR with mesh from 2007 to 2017. Patients whose recorded data included BMI, defect size, and operative approach were included. Defect width was defined as the farthest transverse distance between lateral fascial edges of the hernia defect, as measured intraoperatively. Defect length was defined as the farthest distance between superior and inferior fascial edges of the hernia defect, as measured intraoperatively. Defect area was defined as the product of width and length. Operative outcomes as captured by the IHMR were assessed, including infection, seroma, hematoma, reoperation, and recurrence.

Patient-reported QOL was assessed using the Carolinas Comfort Scale (CCS), a validated hernia-specific scale that addresses short and long-term QOL outcomes after hernia repair (Table 2).[29,30] The CCS addresses 3 symptoms (sensation of mesh, pain, and movement limitation) during 7 activities (bending over, sitting, activities of daily living, coughing or deep breathing, walking, walking upstairs, and exercise), as well as pain and mesh sensation at rest. Each symptom is rated from 0 to 5 on a Likert scale. Zero corresponds to no symptoms and 5 corresponds to debilitating symptoms. The survey is administered before the procedure and at 1, 6, 12, and 24 months postoperatively. A total CCS score ≥2 on any question was considered symptomatic, with non-ideal QOL.

Statistical analysis

Data were analyzed using standard statistical methods using the SAS, version 9.4 (SAS Institute). Descriptive statistics, including mean ± SD and median and interquartile range (IQR) for non-normal or ordinal variables, or counts and percentages for categorical variables, were used to describe the study subjects. For continuous variables, comparisons were made between groups using *t*-tests and Wilcoxon Mann-Whitney tests. For categorical variables, chi-square and Fisher's exact tests were used to make comparisons between groups. For the primary univariate analysis, patient demographics such as age, BMI, diabetes, smoking, steroid use, defect size, and other comorbidities were compared to identify potentially confounding variables. Multivariate logistic regression analysis was performed to control for potentially confounding variables, including operative approach, sex, age, diabetic status, history of hernia recurrence, and ratio of BMI to hernia defect area. Odds ratio (OR) was set to compare outcomes of patients undergoing laparoscopic

Table 3. Operative Outcomes after Ventral Hernia Repair with Mesh

Outcomes	All	Open VHR	Laparoscopic VHR	p Value*
Length of stay, d, median (IQR)	1.0 (0–4.0)	1.0 (0–4.0)	2.0 (1.0–3.0)	0.0002†
Follow-up, mo, median (IQR)	23.2 (11.0–24.9)	23.3 (11.3–25.0)	23.0 (8.9–24.7)	0.08
Hematoma, %	2.04	2.4	1.6	0.31
Seroma, %	10.2	6.6	15.3	<0.0001†
Infection, %	1.9	3.1	0.3	<0.0001†
Recurrence, %	5.3	5.5	5.0	0.6
Reoperation, %	4.2	4.7	3.4	0.20
Non-ideal quality of life,‡ %				
At 1 mo	46.4	39.1	58.0	<0.0001†
At 6 mo	32.0	37.4	28.2	0.007†
At 12 mo	28.1	24.1	34.5	0.0002†
At 24 mo	28.8	25.4	34.5	0.003†

*Univariate analysis by repair type.
†Significant.
‡Non-ideal quality of life defined as a score ≥2 on the Carolinas Comfort Scale.
IQR, interquartile range; VHR, ventral hernia repair.

operation with those of patients undergoing open repair. The level of significance was set at $p < 0.05$ for all comparisons.

The multivariate logistic regression model was constructed with covariates chosen based on univariate results and clinical significance. Multicollinearity between these selected covariates was assessed using the variance inflation factor (VIF). The VIF values >2.5 were considered indicators of substantial multicollinearity, which was undesired in the model. The goodness-of-fit of the final multivariate logistic regression model was assessed via the Hosmer-Lemeshow test and the Somers' D statistic. A p value <0.05 for the Hosmer-Lemeshow test indicates that the model is well calibrated, that is, the model prediction is not significantly different from the observed values. The Somers' D statistics is an estimate of the rank correlation of the observed binary response variable and the predicted probabilities. The properties of the final model were determined by calculating the sensitivity, specificity, percentage correctly classified, adjusted R^2, and area under the receiver operating characteristic curve (AUC). A value of at least 70% for the AUC was considered acceptable for diagnostic accuracy. Internal validation of the multivariate logistic regression model was performed using bootstrap analysis based on 200 replications. The performance of the internal validation was assessed using the Somers' D score and the AUC.

RESULTS

Patient demographics

Between 2007 and 2017, VHR with mesh was performed in 1,906 patients. Patient demographic characteristics are described in Table 2. Male patients accounted for 55.9% of patients undergoing repairs and median age was 56 years (IQR 46 to 65 years). Open procedures accounted for 58.8% of cases and 41.2% were laparoscopic. Hernias were classified as 58.9% ventral, 6.1% epigastric, 29.8% umbilical, and 5.2% other (including epigastric/umbilical, and trochar site). Recurrent hernias accounted for 17.1% of repairs, with 37% of those having had 2 or more earlier repairs. Median BMI was 30.1 kg/m^2 (IQR 26.5 to 35.1 kg/m^2). Mean intraoperative defect width was 5.3 ± 4.9 cm and mean area was 44.8 ± 88.1 cm^2. There was a 10.2% incidence of postoperative seroma, a 4.2% reoperation rate, a 1.9% infection rate, a 5.3% rate of investigator-confirmed recurrence, and a

Table 4. Outcomes of Ventral Hernia Repair as Associated with Operative Approach

Outcomes	Open VHR, reference	Laparoscopic VHR, odds ratio	95% CI
Seroma	1.00	1.78	1.05–3.03†
Infection	1.00	0.05	0.01–0.42†
Reoperation	1.00	0.63	0.29–1.38
Recurrence	1.00	0.89	0.43–1.85
Non-ideal QOL*			
At 1 mo	1.00	1.74	1.17–2.59†
At 6 mo	1.00	1.47	1.06–2.06†
At 12 mo	1.00	2.50	1.44–4.22†
At 24 mo	1.00	2.98	1.64–5.41†

Multivariate logistic regression controlling for age, sex, diabetes, operative approach, BMI to defect area ratio, and history of recurrence.
*Non-ideal quality of life defined as a score ≥2 on the Carolinas Comfort Scale.
†Significant.
QOL, quality of life; VHR, ventral hernia repair.

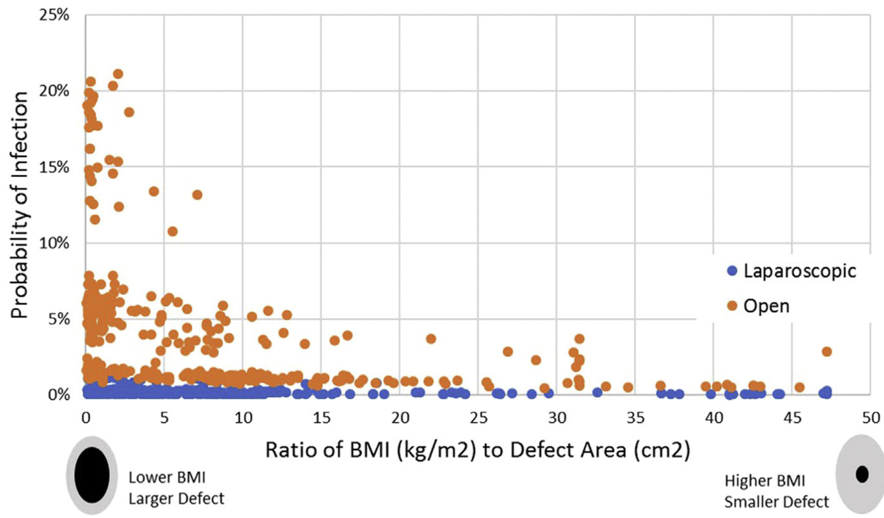

Figure 1. Probability of infection after ventral hernia repair. Multivariate logistic regression controlling for age, sex, diabetic status, primary or recurrent hernia, and a ratio of BMI to defect area.

10.6% patient reported recurrence rate at a median follow-up of 23.2 months (IQR 11.0 to 24.9 months) (Table 3). A total of 73% of patients participated in follow-up at 1 year and 56% participated in follow-up at 24 months.

Univariate analysis

There were multiple significant differences between patients undergoing laparoscopic and open repair (Table 2). Patients undergoing open repair were more likely to be male (61.6% vs 47.8%; $p < 0.0001$), white (93.6% vs 80.6%; $p < 0.0001$), active smokers (19.9% vs 16.8%; $p < 0.0003$), and had larger mean hernia area (46.6 ± 104.5 cm^2 vs 42.6 ± 61.9 cm^2; $p < 0.0001$). Patients undergoing laparoscopic repair had higher median BMI (31.6 kg/m^2; IQR 27.6 to 36.5 kg/m^2 vs 29.4 kg/m^2; IQR 26 to 33.9 kg/m^2; $p < 0.0001$), and were more likely to be morbidly obese (BMI > 40 kg/m^2) (15.1% vs 7.77%; $p < 0.0001$). There were no group differences in history of recurrent hernia, diabetes, and steroid use. There were

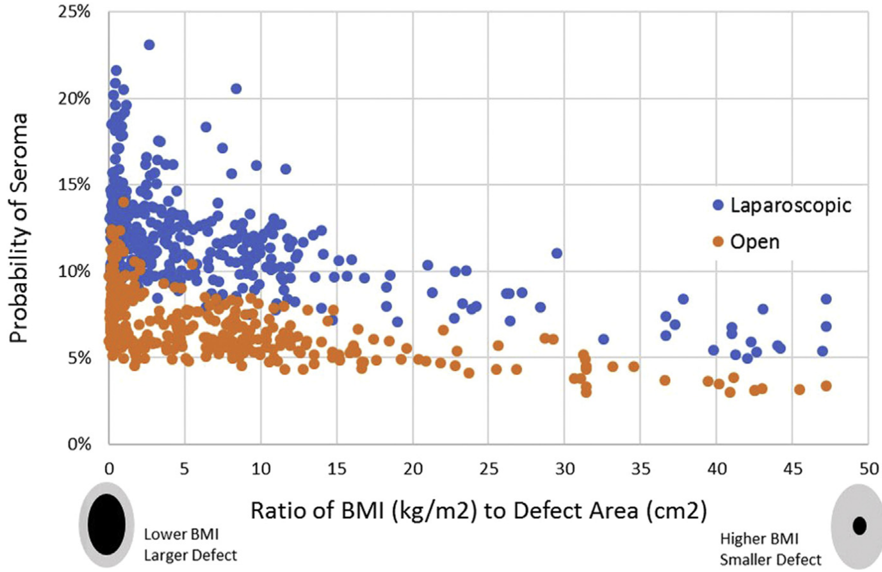

Figure 2. Probability of seroma after ventral hernia repair. Multivariate logistic regression controlling for age, sex, diabetic status, primary or recurrent hernia, and a ratio of BMI to defect area.

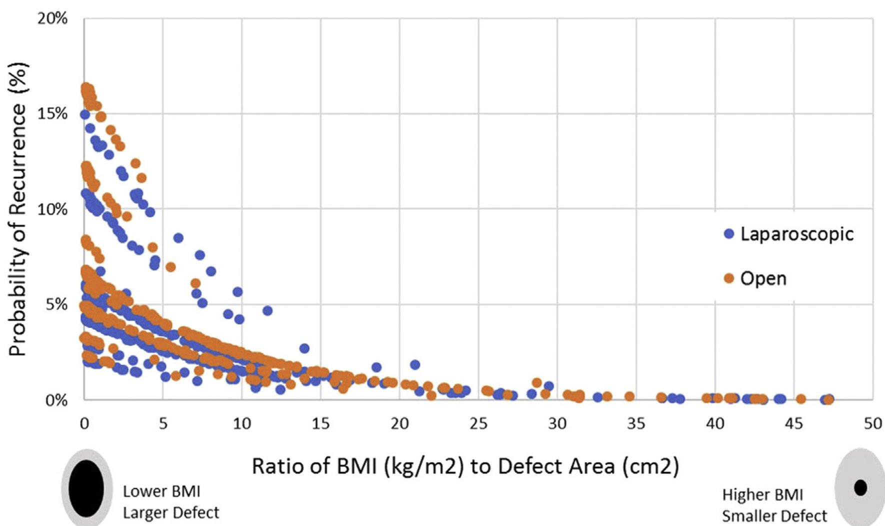

Figure 3. Probability of recurrence after ventral hernia repair. Multivariate logistic regression controlling for age, sex, diabetic status, primary or recurrent hernia, and a ratio of BMI to defect area.

regional differences in proportion of laparoscopic repair performed, but no differences in outcomes when compared by geographic location of repair.

Patients who underwent laparoscopic repair had a longer median length of stay (2 days; IQR 1 to 3 days vs 1 day; IQR 0 to 4 days; $p < 0.0002$), a lower incidence of infection (0.3% vs 3.1%; $p < 0.0001$), and a higher incidence of seroma (15.3% vs 6.6%; $p < 0.0001$) (Table 3). Patient-reported hernia recurrence was higher in the laparoscopic group (13.5% vs 8.5%; $p < 0.0005$), and this trend persisted in the 1,310 patients who were followed for more than 1 year postoperatively (16.1% vs 9.8%; $p < 0.0001$). However, investigator-confirmed recurrence was not significantly different between groups (5.5% open and 5.0% laparoscopic; $p = 0.6$). Patients who underwent LVHR had higher rates of non-ideal QOL at 1, 6, 12, and 24 months (all values, $p < 0.0007$).

Multivariate analysis

Multivariate analysis was performed using variables deemed clinically significant or identified as potentially

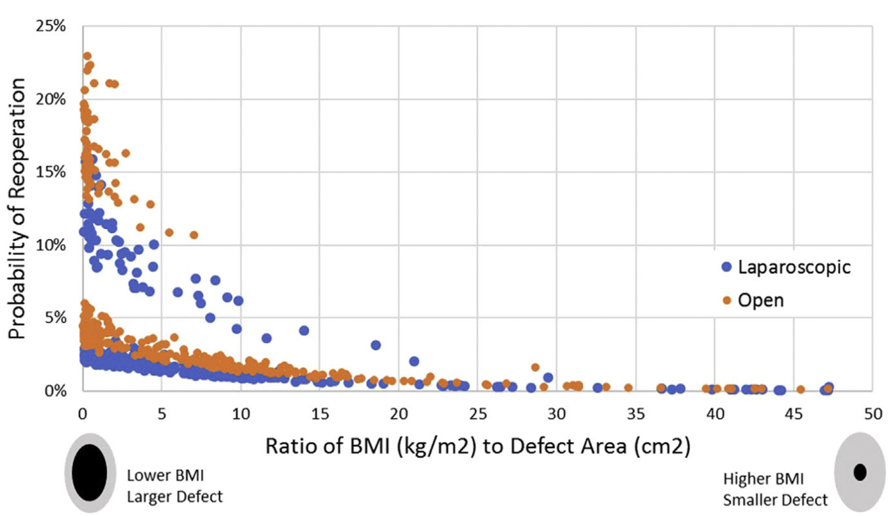

Figure 4. Probability of reoperation after ventral hernia repair. Multivariate logistic regression controlling for age, sex, diabetic status, primary or recurrent hernia, and a ratio of BMI to defect area.

significant in analysis. Variables included operative approach, age, sex, diabetic status, history of hernia recurrence, and ratio of BMI to defect area. When controlling for these potentially confounding variables using multivariate analysis, operative approach impacted operative outcomes significantly (Table 4). The ratio of BMI and defect area was associated with risk of complications and is displayed graphically in Figures 1 through 4. Laparoscopic VHR was associated with non-ideal QOL (CCS $\geq$ 2) at 1, 6, 12, and 24 months of follow-up (all values, $p < 0.05$) (Table 4). The ratio of BMI to defect size was significantly associated with risk of recurrence (OR 0.9; 95% CI 0.817 to 0.991), indicating that larger BMIs with smaller defect had a lower likelihood of recurrence. Patient age, sex, and diabetic status were not consistently associated with operative outcomes on multivariate analysis.

Figure 1 demonstrates the probability of infection after VHR, with each point representing a single patient's risk of infection as calculated with multivariate logistic regression controlling for age, sex, diabetic status, primary or recurrent hernia, and ratio of BMI to defect area. Laparoscopic approach was associated with lower infection rates compared with open repair (OR 0.05; 95% CI 0.01 to 0.42) (Table 4), and the presence of a recurrent hernia was significantly associated with infection compared with primary VHR (OR 3.37; 95% CI 1.08 to 10.54) (Table 5). The risk of infection after open repair trended toward 3 risk groups. High-risk patients (risk of infection 10% to 20%) had a history of recurrent hernias, large defect size (mean 101.8 ± 88.9 cm^2), high BMI (mean 37.8 ± 9.4 kg/m^2) and underwent open VHR. Medium-risk patients (risk of infection 3% to 8%) are patients with mostly primary hernias (66%), undergoing open repair, who have medium-range defect size and BMI (mean defect 63.9 ± 88.7 cm^2, mean BMI 32.0 ± 7.6 kg/m^2). Finally, patients with low risk (0% to 2%) are mostly primary hernia defects with slightly lower BMI and smaller defect size (mean defect 41.7 ± 87.4 cm^2, mean BMI 31.1 ± 6.6 kg/m^2).

Laparoscopic VHR was associated with nearly double the rate of seroma (OR 1.78; 95% CI 1.05 to 3.03) (Table 4), which is illustrated in Figure 2, with each point representing a single patient's calculated risk of seroma by multivariate logistic regression. Risk of seroma had minimal association with BMI to defect area ratio, but showed a strong association with operative approach. The laparoscopic approach and a small BMI to defect area ratio (large defect, lower BMI) were associated with higher incidence of occurrence.

Patients with a history of recurrent hernia had triple the risk of subsequent recurrence (OR 3.07; 95% CI 1.41 to 6.66) (Table 5). The probability of recurrence after VHR is shown in Figure 3. This shows a correlation of recurrence and BMI to defect area ratio, with a lower ratio (small patient, large defect) associated with a higher probability of recurrence. Risk of recurrence follows distinct logarithmic trends as predicted by multivariate analysis, with each line associated with an increasing number of comorbidities (history of recurrence being most predictive).

The presence of a recurrent hernia was significantly associated with need for reoperation (OR 8.5; 95% CI 3.85 to 18.73) (Table 5). An individual patient's risk of reoperation is illustrated in Figure 4. Patients with a history of hernia repair have significantly higher risk of reoperation and represent the majority of patients with a >6% risk of reoperation after both LVHR and OVHR.

Table 5. Outcomes of Ventral Hernia Repair as Associated with History of Recurrence

Outcomes	Primary, reference	Recurrent, odds ratio	95% CI
Seroma	1.00	1.39	0.75–2.58
Infection	1.00	3.37	1.08–10.54†
Reoperation	1.00	4.93	2.24–10.87†
Recurrence	1.00	2.69	1.24–5.81†
Non-ideal quality of life*			
At 1 mo	1.00	1.97	1.17–3.33†
At 6 mo	1.00	1.25	0.84–1.86
At 12 mo	1.00	1.46	0.64–3.11

Multivariate logistic regression controlling for: age, sex, diabetes, operative approach, BMI to defect area ratio, and history of recurrence.
*Non-ideal quality of life is a score ≥2 on the Carolinas Comfort Scale.
†Significant.

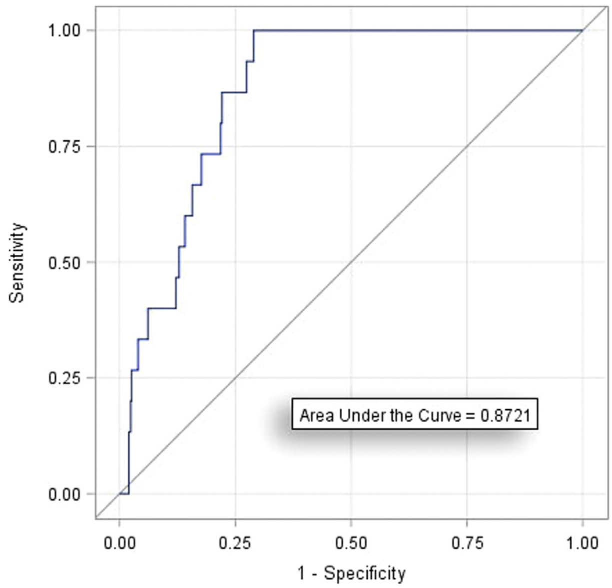

Figure 5. Receiver operating characteristic curve for model for postoperative infection. Area under the curve, 0.8721.

Multivariate predictive model and internal validation

When postoperative infections were examined using multivariate logistic regression, laparoscopic approach ($p = 0.005$) and male sex ($p = 0.02$) were found to be independently protective from infection, and history of recurrent hernia was associated with infection. These predictors had a VIF of 1.04 and demonstrated low correlations. This model demonstrated sensitivity of 73.3%, specificity of 73.3%, 78.2% correctly classified, an adjusted R^2 of 21.02, and an AUC of 0.8721 (95% CI 0.8210 to 0.9231). The Hosmer-Lemeshow goodness-of-fit test had a p value of 0.89 and the Somers' D statistic was 0.74, demonstrating adequate calibration of the model. After internal validation via bootstrap analysis using 200 replications, the optimism value for AUC correction was 0.636, resulting in a corrected AUC of 0.8085, demonstrating good discriminatory power. The bootstrap Somers' D was 0.6594, demonstrating a bias of only 0.0846. The AUC for the final postoperative infection model is displayed in Figure 5. The model calculates the percent risk of postoperative infections as:

$$\textit{Percent risk} = 1/1 + e^{-[-5.0883-1.4566T+0.0139A-0.6901S+0.6077R+0.1067D-0.0213BD]}$$

where:

e: mathematical constant $e \approx 2.71828$
T: surgical technique (open = −1, laparoscopic = 1)
A: age in years
S: sex (female = −1, male = 1)
R: hernia type (primary = −1, recurrent = 1)
D: diabetes (No = −1, Yes = 1)
BD: BMI to hernia defect size ratio

History of recurrent hernia was significantly predictive of need for reoperation ($p < 0.0001$). This predictor had a VIF of 1.05 and demonstrated low correlation. This model demonstrated sensitivity of 63.6%, specificity of 74.1%, 73.6% correctly classified, an adjusted R^2 of 14.8%, and an AUC of 0.7726 (95% CI 0.6875 to 0.8576). The Hosmer-Lemeshow goodness-of-fit test had a p value of 0.84 and the Somers' D statistic was 0.54, demonstrating adequate calibration of the model. After internal validation via bootstrap analysis using 200 replications, the optimism value for AUC correction was 0.375, resulting in a corrected AUC of 0.7351, demonstrating good discriminatory power. The bootstrap Somers' D was 0.5149, demonstrating a bias of only 0.0301. The AUC for the final postoperative reoperation is displayed in Figure 6. The model calculates the percent risk of reoperation as:

$$\textit{Percent risk} = 1/1 + e^{-[-2.8454-0.2297T+0.0058A-0.1147S+0.7976R+0.1439D-0.0816BD]}$$

where:

e: mathematical constant $e \approx 2.71828$
T: surgical technique (open = −1, laparoscopic = 1)
A: age in years
S: sex (female = −1, male = 1)
R: hernia type (primary = −1, recurrent = 1)
D: diabetes (No = −1, Yes = 1)
BD: BMI to hernia defect size ratio

A model was created that predicted hernia recurrence as influenced by factors listed here. History of recurrent hernia was significantly predictive of subsequent recurrence ($p < 0.01$). This predictor had a VIF of 1.07 and demonstrated low correlation. This model demonstrated sensitivity of 53.6%, specificity of 72.1%, 71.4% correctly classified, an adjusted R^2 of 8.79%, and an AUC of 0.7125 (95% CI 0.62 to 0.80). The Hosmer-Lemeshow goodness-of-fit test had a p value of 0.65 and the Somers' D statistic was 0.42, demonstrating adequate calibration of the model. After internal validation via bootstrap analysis using 200 replications, the optimism value for AUC correction was 0.458, resulting in a corrected AUC of 0.6669, demonstrating insufficient discriminatory power. The bootstrap Somers' D was also lowered at 0.3823, demonstrating a bias of 0.427. The AUC for the final recurrence model is displayed in Figure 7. The model calculates the percent risk of hernia recurrence as:

$$\textit{Percent risk} = 1/1 + e^{-[-2.8199-0.0606T+0.0013A+0.1695S+0.4950R-0.3828D-0.1054BD]}$$

where:

e: mathematical constant $e \approx 2.71828$
T: surgical technique (open = −1, laparoscopic = 1)
A: age in years
S: sex (female = −1, male = 1)
R: hernia type (primary = −1, recurrent = 1)
D: diabetes (no = −1, yes = 1)
BD: BMI to hernia defect size ratio

DISCUSSION

This investigation of nearly 2,000 mesh-reinforced hernia repairs from an international hernia registry reveals and reaffirms predictors of adverse outcomes after VHR. In this data set, LVHR is performed more often in obese patients. Although LVHR is associated with fewer infections, there are more seromas and higher incidence of patient-reported hernia recurrence. Laparoscopic VHR

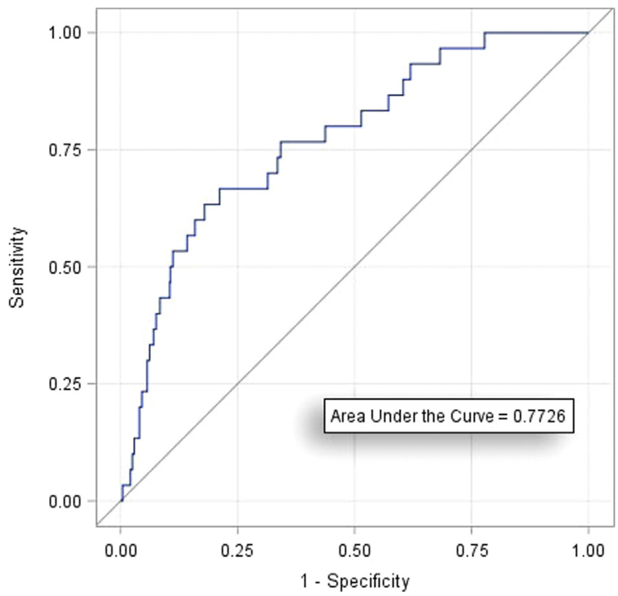

Figure 6. Receiver operating characteristic curve for model for reoperation. Area under the curve, 0.7726.

is associated with worse QOL than OVHR when patients are surveyed up to 2 years after operation, indicating that patients experience pain, mesh sensation, and movement limitation long after the initial recovery period. Hernia characteristics significantly impact outcomes, with large defects associated with non-ideal postoperative QOL in both open and laparoscopic approaches.[31] History of previous repair is found to predict need for reoperation and ultimate recurrence.[32,33] Risk of infection, reoperation, and recurrence increases with recurrent hernias, larger defect size, and OVHR compared with LVHR. When multivariate analysis was performed to control for confounding factors in this cohort, diabetes and smoking status were not found to independently impact outcomes after repair. This finding is not consistent with multiple previous studies and might be due to incomplete capture of preoperative optimization (smoking cessation and improved glycemic control), and/or a relatively low overall complication rate precluding the detection of real but small differences in outcomes.

Historically, LVHR has been associated with lower infection rate, higher incidence of seroma, worse QOL, and potentially higher recurrence rate.[2,5,7,12,15,34] When small and medium size defects were examined, patients had demonstrably lower risk of complications when undergoing LVHR (Table 6). A cohort of OVHR patients with a moderate risk of infection (3% to 8%) were identified using the scatterplot of risk of infection (Figure 1), as calculated by the multivariate regression model. The risk of infection was re-calculated, had these operations been performed laparoscopically and found that switching from open to laparoscopic approach lowered the likelihood of infection dramatically (0.1% to 0.5%). Although operative approach might have been influenced by comorbidities not captured by this data set or analysis, these patients with moderate risk of infection (as influenced by risk factors of age, BMI, defect size, and hernia recurrence) might have benefitted significantly from LVHR with respect to postoperative infection.

In patients with large defects, a lesser clinical difference in outcomes between OVHR and LVHR is seen. Risk of infection, reoperation, and recurrence are higher for patients undergoing OVHR, but the clinical difference is less dramatic (Table 6). The optimal operative approach for obese and otherwise comorbid patients with medium to large hernia defects is particularly difficult and especially important, given the frequency and cost of complications. Morbidly obese patients with larger defects are at higher risk of recurrence after laparoscopic repair, as described by Heniford and colleagues,[35] with patients with BMI >40 kg/m^2 experiencing 4 times the incidence of recurrence after laparoscopic repair. These patients can benefit from fascial closure at the time of hernia repair.[14,16]

When first introduced in the 1990s, LVHR was anticipated to decrease postoperative discomfort. Subsequent studies have shown consistently worse short-term QOL after LVHR compared with OVHR at 1 and 6 months, and this study confirms a significant difference at up to 2 years of follow-up.[6,33,36,37] The association of LVHR

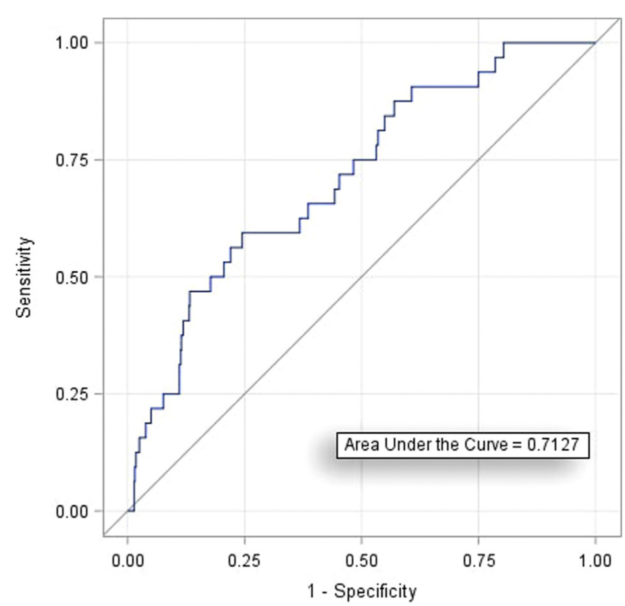

Figure 7. Receiver operating characteristic curve for model for recurrence. Area under the curve, 0.7127.

Table 6. Demonstration of Predictive Models for Infection, Reoperation, and Recurrence*

Predictive model*		% Risk of infection	% Risk of reoperation	% Risk of recurrence
Laparoscopic approach				
BMI: 29.7 kg/m^2 Age: 70 y Sex: female	Defect area: 15.7 cm^2 Diabetes: no Primary hernia	0.4	2.5	3.6
BMI: 28.7 kg/m^2 Age: 71 y Sex: female	Defect area: 15.7 cm^2 Diabetes: no Recurrent hernia	1.2	11.5	9.4
BMI: 33.3 kg/m^2 Age: 69 y Sex: male	Defect area: 226.2 cm^2 Diabetes: no Primary hernia	0.09	2.3	6.0
BMI: 35.5 kg/m^2 Age: 58 y Sex: female	Defect area: 301.6 cm^2 Diabetes: no Recurrent hernia	1.0	12.2	10.8
Open approach				
BMI: 34.7 kg/m^2 Age: 70 y Sex: male	Defect area: 15.7 cm^2 Diabetes: no Primary hernia	1.6	3.1	5.5
BMI: 35.9 kg/m^2 Age: 60 y Sex: male	Defect area: 15.7 cm^2 Diabetes: no Recurrent hernia	4.6	12.9	13.3
BMI: 28 kg/m^2 Age: 77 y Sex: male	Defect area: 235.6 cm^2 Diabetes: no Primary hernia	1.8	3.8	6.8
BMI: 32.6 kg/m^2 Age: 73 y Sex: male	Defect area: 230.9 cm^2 Diabetes: no Recurrent hernia	5.7	16.0	16.4

*Demonstrative patients selected from International Hernia Mesh Registry and predictive algorithm applied.

with non-ideal postoperative QOL is confirmed in the current study by rigorous postoperative assessment at multiple time points in a validated, patient-reported, hernia-specific survey, and must be considered when weighing other operative factors.[30]

This data set unfortunately does not reliably capture fascial closure for either technique, or the extent of mesh overlap. The patient-reported recurrence rate was significantly higher than investigator-confirmed hernia recurrence, which might be due to seroma or bulging mesh after laparoscopic repair without fascial closure. Many laparoscopic approaches do not attempt to achieve primary fascial closure, despite its demonstrated association with decreased recurrence rates.[16,38-41] Techniques for LVHR with primary fascial closure include hybrid approaches with laparoscopic mesh placement and open fascial closure, laparoscopic component separation, and laparoscopic intracorporeal suturing of the fascial defect.[41-43] This technique is associated with decreased recurrence, bulging, and seroma compared with non-closure. Robotic-assisted surgery can alleviate some of the technical difficulties of this approach and can also place meshes in extraperitoneal positions. Successful minimally invasive approaches can avoid the increased surgical site infection and surgical site occurrence, and avoid the complications associated with subsequent hernia recurrence.[14-16] All of these have the potential to positively impact long-term patient QOL.

This study illustrates the interaction of operative technique and risk factors for adverse outcomes. The association of LVHR with decreased postoperative infection is validated on univariate analysis, multivariate analysis, and multivariate predictive modeling. A history of recurrent hernia was the single most predictive factor for subsequent recurrence regardless of operative approach. The need for reoperation was significantly influenced by operative approach and by history of recurrent hernias. Investigator-confirmed hernia recurrence was 5.3% at 2 years of follow-up, with a mean follow up of more than 23 months. This recurrence rate is similar to outcomes reported previously using this and other databases.[2-4] The interaction of patient dimensions as expressed by ratio of BMI to defect area was consistently associated with adverse outcomes, with low ratios (thin patients, large area) predictive of more complications.

The operative outcomes captured and examined by this study are collected from more than 30 surgical centers on 4 continents, and the use of this prospective, hernia-specific database is a significant strength of this study. The contribution of multiple centers allows for a significantly larger cohort and eliminates the single-center bias, which can limit the external validity of findings. The collection of QOL outcomes is designed to avoid physician influence and uses a disease-specific tool for hernia repair. These data are limited by which patients and physicians report outcomes and what observations are entered. Decreased participation over time can lead to an underestimation of complications when patients present elsewhere, but extensive follow-up due to prolonged complications and their sequelae can lead to overrepresentation of complications. The factors influencing surgeon decision to proceed with OVHR vs LVHR might not be fully captured in this database. Follow-up of 70% of patients at 1 year and >50% of patients at 2 years adds to the overall quality of the data.

CONCLUSIONS

This study demonstrates a decreased incidence of multiple complications with a laparoscopic approach and validates predictive models for infection and reoperation after both LVHR and OVHR. The ratio of BMI to defect size is associated with multiple outcomes, as patients with a low ratio of BMI to defect size (lower BMI, larger defect) have higher risk of infection, seroma, recurrence, and reoperation (Figs. 1 to 4) after both LVHR and OVHR. Patients with a history of hernia recurrence are at high risk of subsequent recurrence and an operative approach should include factors to ameliorate this risk, including diabetes control and primary fascial closure. As infectious risk is significantly associated with history of recurrent hernia and obesity, LVHR should be considered when possible in this patient population. In patients with high BMI to defect size ratio, there is a lower incidence of infection, higher incidence of seroma, and no demonstrable difference in incidence of recurrence and reoperation between LVHR and OVHR. Patients who could significantly benefit from a laparoscopic approach include those with defect size near 60 cm^2 or smaller, BMI around 32 kg/m^2, and history of other comorbidities, such as diabetes, advanced age, or recurrent hernia. These patients have a calculated risk of infection of 3% to 8% when undergoing open VHR, but <1% when undergoing LVHR. Laparoscopic approach should be attempted whenever possible in patients with medium risk of infection.

Author Contributions

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Analysis and interpretation of data: Schlosser, Prasad, Augenstein

Drafting of manuscript: Schlosser, Augenstein

Critical revision: Schlosser, Arnold, Otero, Prasad, Colavita, Kercher, Heniford, Augenstein

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